(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 February 2001 (08.02.2001)

PCT

(10) International Publication Number
WO 01/08736 A1

(51) International Patent Classification[7]: A61M 16/00, A62B 9/02

(21) International Application Number: PCT/US00/21073

(22) International Filing Date: 3 August 2000 (03.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/146,863 3 August 1999 (03.08.1999) US

(71) Applicant: THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK [US/US]; State University of New York At Buffalo, Suite 220 UB Commons, 520 Lee Entrance, Amherst, NY 14228 (US).

(72) Inventors: FURHMAN, Bradley, P.; 83 Ashland Avenue, Buffalo, NY 14222 (US). DOWHY, Mark, S.; 725 W. Ferry Street, Buffalo, NY 14222 (US).

(74) Agents: ROBERTS, R., Kent et al.; Hodgson, Russ, Andrews, Woods & Goodyear, LLP, One M & T Plaza, Suite 2000, Buffalo, NY 14203-2391 (US).

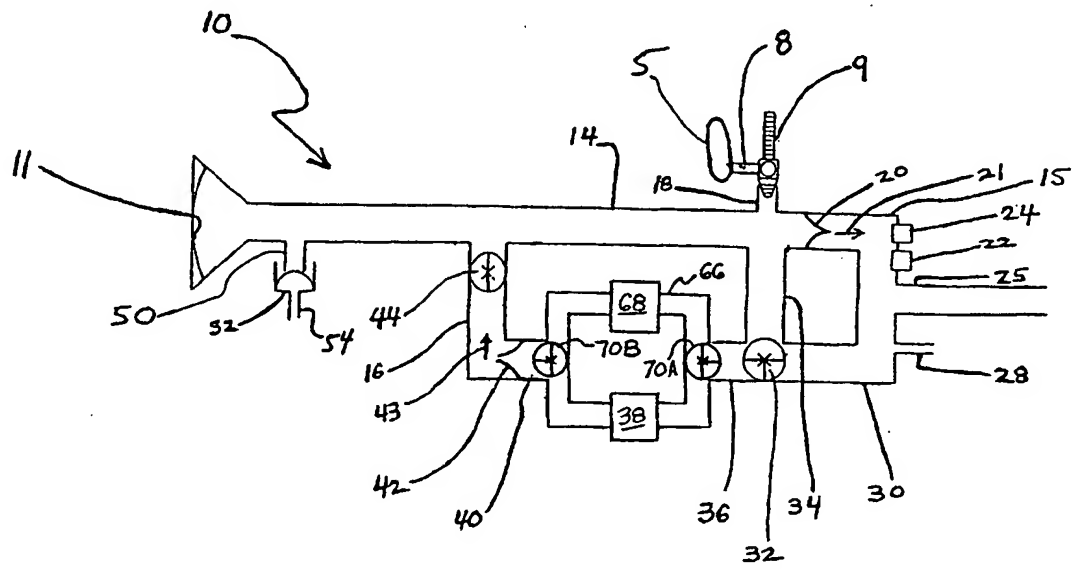
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *With international search report.*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: DEVICE AND METHOD OF REDUCING BIAS FLOW IN OSCILLATORY VENTILATORS




(57) Abstract: A device and method of ventilating a patient reduces the bias flow relative to existing oscillatory ventilators. The device has an oscillator (11), and an oscillating line (14) having a first end in sealing relationship with the oscillator. A gas supply line (8) is connected to the oscillating line, and a patient line (25) is connected to a second end of the oscillating line. An outlet valve (52) is in pneumatic communication with the patient line.

WO 01/08736 A1

of the diaphragm to the gas source and the patient's airway is provided.

In the prior art, inspiratory gas is moved into and out of the patient via a U-shaped tube and movement of the diaphragm. For purposes of describing the prior art, the U-shaped tube can be described as having a first limb with a distal end, a second limb with a distal end, and a tube between the limbs. Connected to the tube between the limbs is another tube (the "patient line") that delivers gas from the U-shaped tube to the patient and also delivers gas from the patient to the U-shaped tube. The patient line may be connected to the patient via an endotracheal tube. The distal end of the first limb is placed in sealing relation to the diaphragm so that gas inside the U-shaped tube is caused to oscillate as the diaphragm moves back and forth. Gas suitable for inspiration ("inspiratory gas") is supplied at a location on the U-shaped tube between the diaphragm and the patient line.

Inspiratory gas passes through the first limb of the U-shaped tube, and exhaled gas exits to the atmosphere through the second limb of the U-shaped tube and out of the distal end of the second limb. To prevent expired gases from being drawn back into the first limb during the expiratory phase of breathing, more inspiratory gas than needed by the patient is provided in order to move the expired gas into the second limb. The inspiratory gas provided in excess of the needs of the patient is referred to herein as "bias flow".

To move expired gas into the second limb of the U-shaped tube, an inspiratory gas flow rate of approximately 20 liters per minute is used when ventilating infants, and as much as 60 to 80 liters per minute when ventilating older children and adults. Such

## BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and objects of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings, in which:

Figure 1 is a schematic sectional view of a device according to the present invention illustrating the major components of the device and utilizing a $CO_2$ scrubber;

Figures 2a and 2b are schematic sectional representations of the closed and open positions respectively of an outlet valve according to the present invention;

Figure 3a is a schematic sectional representation of another embodiment of the present invention;

Figure 3b is a schematic sectional representation of another embodiment of the present invention;

Figures 4a and 4b are schematic sectional views of other embodiments of the present invention having a $CO_2$ scrubber;

Figure 5 is a schematic sectional representation of another embodiment of the present invention.

Figure 6 is a schematic sectional view of another embodiment of the invention without a $CO_2$ scrubber;

Figures 7a and 7b are schematic sectional representations of the closed and open positions respectively of another outlet valve according to the present invention; and

Figure 8 is a flow chart showing steps of a method according to the present invention.

inbound check valve 20 shuts, effectively stopping the flow of gas through inbound line 15.

Further downstream of inbound check valve 20, for example along inbound line 15 may be placed an $O_2$ sensor 24 and a $CO_2$ sensor 22 to monitor the quality of the gas therein. Additional modifiers and monitors like humidifiers, nebulizers and the like can also be installed. Inbound line 15 connects to patient line 25, which is in turn connected to an endotracheal tube (not shown in Figure 1) for delivery of gas to the patient's airways, and ultimately to the patient's lungs.

Inbound line 15 is also connected to exhalation line 30. In exhalation line 30 may be placed a pressure monitoring device, such as a manometer, through port 28. Exhalation line 30 includes a scrubber line 36 and connects to recirculation line 34. Recirculation line 34 connects to the oscillating line 14. At the junction of recirculation line 34 and scrubber line 36 is a two-position valve 32 which directs the flow of gas either toward the recirculation line 34 or toward the scrubber line 36. The two position valve 32 is normally positioned to direct the flow of gas to the scrubber line 36. Preferably, the two-position valve 32 is normally adjusted so that no gas flows through recirculation line 34.

Included in the exhalation line 30 is a scrubber canister 38, an outbound line 40, and a discharge line 16. A second scrubber 68 may also be included and used when the scrubber canister 38 is not being used, for example, while scrubber canister 38 is being replaced or recharged, for example, by purging $CO_2$ using a separate

line 54 by the oscillating machine that controls the oscillator 11. In one embodiment of the present invention, the control pressure provided by line 54 is substantially stable and the oscillating pressure in line 14 caused by movement of the diaphragm 11 causes the outlet valve 52 to open and close. Alternatively, operation of the outlet valve 52 may be by other means, such as a solenoid.

High frequency oscillation of the oscillator 11 facilitates movement of gas into and out of the patient's airways. Thus, during the inspiration phase, when the oscillator 11 is moving toward the oscillating line 14, a pressurizing cycle occurs, and during the expiration phase, when the oscillator 11 is moving away from the oscillating line 14, a depressurizing cycle occurs. During the pressurizing cycle, the pressure on the upstream side of the inbound check valve 20 increases, forcing it to open thereby allowing gas to flow in the direction of arrow 21, and consequently into the patient's lungs via patient line 25. At the same time, due to the oscillator 11 moving toward the device 10, the pressure on the downstream side of outbound check valve 42 becomes higher than the pressure on its upstream side, which forces the outbound check valve 42 to close, thereby preventing the flow of gas from discharge line 16 into the scrubber canister 38.

During the expiration phase (or depressurizing part of the cycle), the oscillator 11 moves away from the oscillating line 14 and the pressure differential across the inbound check valve 20 causes the inbound check valve 20 to close. The exhaled gas is pushed by the

due to movement of the oscillator **11** toward the device **10**).

The $CO_2$ scrubber canister **38** in the device **10** of the present invention may be used in other locations. For example, as shown in Figures 3a and 3b, the scrubber canister **38** may be placed at the end of patient line **25** distal from the inbound line **15**, and preferably between the patient line **25** and the endotracheal tube **60**. As shown in Figure 3a, suitable check valves **20**, **42** and return line **67** can be incorporated to assure unidirectional flow through the scrubber canister **38**. As shown in Figures 3a and 3b, a bypass line **66** could be provided to accommodate replacement of the scrubber canister **38**. In a preferred embodiment of the present invention, the second scrubber canister **68** is provided in the bypass line **66**. The second scrubber canister **68** may be incorporated into any embodiment described herein which has a scrubber canister **38**. The device depicted in Figures 3a and 3b could be used with prior art ventilator circuits.

The scrubber canister **38** contains a material that removes unwanted gas, such as $CO_2$. For example, the scrubber canister **38** may contain sodium hydroxide, calcium hydroxide, or barium hydroxide. Sodium hydroxide and calcium hydroxide mixed with silica is available as Soda Lime™. Another commercially available $CO_2$ scrubber is Baralyme™ which comprises barium hydroxide and calcium hydroxide. Once the $CO_2$ scrubber canister **38** is depleted of its scrubbing capacity, it can be replaced. To replace the scrubber canister **38**, the two-position valve **32** is set to direct the gas from

the exhaled gas, the exhaled gas is simply allowed to leave a device **100**. The device **100** is connected to an inspiratory gas source **5** through connecting line **18**. The inspiratory gas enters an oscillating line **14** and moves toward the patient line **25** in the direction of arrow **21** via the inbound check valve **20**. $CO_2$ and $O_2$ sensors **22, 24** and pressure monitoring port **28** can be placed near the patient line **25**. The exhaled gas is conducted by the exhalation line **30** to another type of outlet valve **52**. The outlet valve **52** shown in Figures 6, 7a and 7b operates based on the pressure differential between oscillating line **14** and the exhalation line **30**. During the pressurizing cycle, outlet valve **52** is caused to close the end **132** of exhalation line **30** by the rising pressure in oscillating line **14**. However, during the depressurizing phase, the pressure in the outlet line **50** causes the outlet valve **52** to open the end **132** and allow gas to escape to the atmosphere. Preferably, for at least part of the pressurization cycle, outlet valve **52** is closed and there is no communication between the exhalation line **30** and the atmosphere, and for at least part of the depressurization cycle, outlet valve **52** is open and there is communication between line **30** and the atmosphere.

Figures 7a and 7b show a preferred embodiment of the outlet valve **52** shown in Figure 6. The outlet valve **52** in Figures 7a and 7b has a first flexible membrane **300** disposed in the oscillating line **14** and a second flexible membrane **303** situated to selectively close the end **132** of the outlet line **50**. The flexible membranes

$FmO_2$ is the mole fraction of oxygen in the mixed gas crossing inbound check valve **20**;

$FiO_2 = 1-FiN_2$, where $FiN_2$ is the mole fraction of nitrogen in the inspiratory gas;

$FmO_2 = 1-FmN_2$, where $FmN_2$ is the mole fraction of nitrogen in the mixed gas exiting the outlet valve **52**;

$VI = K + VO_2$, where K = outflow volume from outlet valve **52**;

$$VI \times FiN_2 = K \times FmN_2;$$
$$VI(1-FiO_2) = K(1-FmO_2);$$
$$(VI \div K)(1-FiO_2) = 1-FmO_2;$$
$$FmO_2 = 1-((VI \div K)(1-FiO_2)).$$

Table 1

| $VO_2$ ml/kg/min | VI ml/kg/min | $FiO_2$ | $FmO_2$ | $FmO_2 \div FiO_2$ | K ml/kg/min | $VI \div VO_2$ |
|---|---|---|---|---|---|---|
| 5.0 | 6.0 | 0.21 | -3.74 | -17.81 | 1.0 | 1.2 |
| 5.0 | 10.0 | 0.21 | -0.58 | -2.76 | 5.0 | 2.0 |
| 5.0 | 20.0 | 0.21 | -0.05 | -0.25 | 15.0 | 4.0 |
| 5.0 | 30.0 | 0.21 | 0.05 | 0.25 | 25.0 | 6.0 |
| 5.0 | 40.0 | 0.21 | 0.10 | 0.46 | 35.0 | 8.0 |
| 5.0 | 50.0 | 0.21 | 0.12 | 0.58 | 45.0 | 10.0 |
| 5.0 | 60.0 | 0.21 | 0.14 | 0.66 | 55.0 | 12.0 |
| 5.0 | 70.0 | 0.21 | 0.15 | 0.71 | 65.0 | 14.0 |
| 5.0 | 80.0 | 0.21 | 0.16 | 0.75 | 75.0 | 16.0 |
| 5.0 | 90.0 | 0.21 | 0.16 | 0.78 | 85.0 | 18.0 |
| 5.0 | 100.0 | 0.21 | 0.17 | 0.80 | 95.0 | 20.0 |
| 5.0 | 200.0 | 0.21 | 0.19 | 0.90 | 195.0 | 40.0* |
| 5.0 | 500.0 | 0.21 | 0.20 | 0.96 | 495.0 | 100.0 |
| 5.0 | 1000.0 | 0.21 | 0.21 | 0.98 | 995.0 | 200.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 5.0 | 70.0 | 0.40 | 0.35 | 0.88 | 65.0 | 14.0 |
| 5.0 | 80.0 | 0.40 | 0.36 | 0.90 | 75.0 | 16.0* |
| 5.0 | 90.0 | 0.40 | 0.36 | 0.91 | 85.0 | 18.0 |
| 5.0 | 100.0 | 0.40 | 0.37 | 0.92 | 95.0 | 20.0 |
| 5.0 | 200.0 | 0.40 | 0.38 | 0.96 | 195.0 | 40.0 |
| 5.0 | 500.0 | 0.40 | 0.39 | 0.98 | 495.0 | 100.0 |
| 5.0 | 1000.0 | 0.40 | 0.40 | 0.99 | 995.0 | 200.0 |

Table 4

| VO2 ml/kg/ min | VI ml/kg/ min | $FiO_2$ | $FmO_2$ | $FmO_2 \div FiO_2$ | K ml/kg/ min | $VI \div VO_2$ |
|---|---|---|---|---|---|---|
| 5.0 | 6.0 | 0.50 | -2.00 | -4.00 | 1.0 | 1.2 |
| 5.0 | 10.0 | 0.50 | 0.00 | 0.00 | 5.0 | 2.0 |
| 5.0 | 20.0 | 0.50 | 0.33 | 0.67 | 15.0 | 4.0 |
| 5.0 | 30.0 | 0.50 | 0.40 | 0.80 | 25.0 | 6.0 |
| 5.0 | 40.0 | 0.50 | 0.43 | 0.86 | 35.0 | 8.0 |
| 5.0 | 50.0 | 0.50 | 0.44 | 0.89 | 45.0 | 10.0 |
| 5.0 | 60.0 | 0.50 | 0.45 | 0.91 | 55.0 | 12.0* |
| 5.0 | 70.0 | 0.50 | 0.46 | 0.92 | 65.0 | 14.0 |
| 5.0 | 80.0 | 0.50 | 0.47 | 0.93 | 75.0 | 16.0 |
| 5.0 | 90.0 | 0.50 | 0.47 | 0.94 | 85.0 | 18.0 |
| 5.0 | 100.0 | 0.50 | 0.47 | 0.95 | 95.0 | 20.0 |
| 5.0 | 200.0 | 0.50 | 0.49 | 0.97 | 195.0 | 40.0 |
| 5.0 | 500.0 | 0.50 | 0.49 | 0.99 | 495.0 | 100.0 |
| 5.0 | 1000.0 | 0.50 | 0.50 | 0.99 | 995.0 | 200.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 5.0 | 70.0 | 0.70 | 0.68 | 0.97 | 65.0 | 14.0 |
| 5.0 | 80.0 | 0.70 | 0.68 | 0.97 | 75.0 | 16.0 |
| 5.0 | 90.0 | 0.70 | 0.68 | 0.97 | 85.0 | 18.0 |
| 5.0 | 100.0 | 0.70 | 0.68 | 0.98 | 95.0 | 20.0 |
| 5.0 | 200.0 | 0.70 | 0.69 | 0.99 | 195.0 | 40.0 |
| 5.0 | 500.0 | 0.70 | 0.70 | 1.00 | 495.0 | 100.0 |
| 5.0 | 1000.0 | 0.70 | 0.70 | 1.00 | 995.0 | 200.0 |

Table 7

| VO2 ml/kg/ min | VI ml/kg/ min | $FiO_2$ | $FmO_2$ | $FmO_2 \div FiO_2$ | K ml/kg/ min | $VI \div VO_2$ |
|---|---|---|---|---|---|---|
| 5.0 | 6.0 | 0.80 | -0.20 | -0.25 | 1.0 | 1.2 |
| 5.0 | 10.0 | 0.80 | 0.60 | 0.75 | 5.0 | 2.0 |
| 5.0 | 20.0 | 0.80 | 0.73 | 0.92 | 15.0 | 4.0* |
| 5.0 | 30.0 | 0.80 | 0.76 | 0.95 | 25.0 | 6.0 |
| 5.0 | 40.0 | 0.80 | 0.77 | 0.96 | 35.0 | 8.0 |
| 5.0 | 50.0 | 0.80 | 0.78 | 0.97 | 45.0 | 10.0 |
| 5.0 | 60.0 | 0.80 | 0.78 | 0.98 | 55.0 | 12.0 |
| 5.0 | 70.0 | 0.80 | 0.78 | 0.98 | 65.0 | 14.0 |
| 5.0 | 80.0 | 0.80 | 0.79 | 0.98 | 75.0 | 16.0 |
| 5.0 | 90.0 | 0.80 | 0.79 | 0.99 | 85.0 | 18.0 |
| 5.0 | 100.0 | 0.80 | 0.79 | 0.99 | 95.0 | 20.0 |
| 5.0 | 200.0 | 0.80 | 0.79 | 0.99 | 195.0 | 40.0 |
| 5.0 | 500.0 | 0.80 | 0.80 | 1.00 | 495.0 | 100.0 |
| 5.0 | 1000.0 | 0.80 | 0.80 | 1.00 | 995.0 | 200.0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 5.0 | 70.0 | 1.00 | 1.00 | 1.00 | 65.0 | 14.0 |
| 5.0 | 80.0 | 1.00 | 1.00 | 1.00 | 75.0 | 16.0 |
| 5.0 | 90.0 | 1.00 | 1.00 | 1.00 | 85.0 | 18.0 |
| 5.0 | 100.0 | 1.00 | 1.00 | 1.00 | 95.0 | 20.0 |
| 5.0 | 200.0 | 1.00 | 1.00 | 1.00 | 195.0 | 40.0 |
| 5.0 | 500.0 | 1.00 | 1.00 | 1.00 | 495.0 | 100.0 |
| 5.0 | 1000.0 | 0.00 | 1.00 | 1.00 | 995.0 | 200.0 |

Table 10

| VO2 ml/kg /min | VI ml/kg /min | $FiO_2$ | $FmO_2$ | $FmO_2 \div FiO_2$ | K ml/kg /min | $VI \div VO_2$ | Tole-rance |
|---|---|---|---|---|---|---|---|
| 5.0 | 200.0 | 0.21 | 0.19 | 0.90 | 195.0 | 40.0 | 10% |
| 5.0 | 200.0 | 0.30 | 0.28 | 0.94 | 195.0 | 40.0 | 10% |
| 5.0 | 80.0 | 0.40 | 0.36 | 0.90 | 75.0 | 16.0 | 10% |
| 5.0 | 60.0 | 0.50 | 0.45 | 0.91 | 55.0 | 12.0 | 10% |
| 5.0 | 40.0 | 0.60 | 0.54 | 0.90 | 35.0 | 8.0 | 10% |
| 5.0 | 30.0 | 0.70 | 0.64 | 0.91 | 25.0 | 6.0 | 10% |
| 5.0 | 20.0 | 0.80 | 0.73 | 0.92 | 15.0 | 4.0 | 10% |
| 5.0 | 20.0 | 0.90 | 0.87 | 0.96 | 15.0 | 4.0 | 10% |
| 5.0 | 6.0 | 1.00 | 1.00 | 1.00 | 1.0 | 0.83 | 10% |

Tables 1-9 illustrate the $FmO_2$ achieved at various inspiratory gas flow rates (VI) assuming an oxygen consumption rate of 5 ml/kg/min. An asterisk in the column labeled $VI/VO_2$ indicates the minimum flow rate of inspiratory gas needed to achieve an FmO2 that is within 10% of the corresponding $FiO_2$. The inspiratory gas corresponding to Table 1 was air (21% oxygen). As seen in Table 1, an inspiratory gas flow rate of 50 ml/kg/min results in the fraction of $O_2$ in the mixed gas (mixture of inspiratory gas and scrubbed exhaled gas) to be about

oscillator is moved toward the oscillating line and the outlet valve is opened (step 209). Then, the oscillator is moved away from the oscillating line and the outlet valve is closed (step 212). Preferably, the gas is supplied to the oscillating line at approximately a constant flow rate.

Devices and methods according to the present invention are more efficient than currently available high frequency oscillating ventilators primarily because the present invention substantially reduces the need for bias flow. This reduction in bias flow enables smaller ventilation systems. It is now clear the device and method of the present invention reduces the volume of bias flow required for safe ventilation. By using the present device, it is believed the volume of inspiratory gas delivered to the ventilator can be reduced from 20,000 to 80,000 ml/min to as little as 20 to 800 ml/min.

Another advantage of the present invention may be to counter the loss of mean lung volume associated with prolonged oscillatory ventilation, which is believed to be a problem with this form of mechanical ventilation. It is currently believed by some that this problem might be intensified by reductions in inspiratory gas flow. One approach to this problem that may counter a tendency to lose mean lung volume and thus preserve lung expansion involves redirection of some or all of the inspiratory gas flow to a small channel adapted to the endotracheal tube to allow delivery of some or all of the bias flow directly to the trachea. While potentially hazardous at high (conventional) inspiratory gas flow rates, it is believed that this would be safe at the lower inspiratory gas flow rates envisioned for this invention. Moreover, it is recognized that there might be some advantage to redirecting some or all of

What is claimed is:

1. A ventilating device, comprising:
an oscillator;
an oscillating line having a first end and a second end, the first end is in sealing relationship with the oscillator;
a gas supply line connected to the oscillating line at a first location and connected to a supply of gas;
a patient line connected to the second end of the oscillating line; and
an outlet valve in pneumatic communication with the patient line; and
a $CO_2$ scrubber in pneumatic communication with the patient line.

2. The device of claim 1, further comprising a check valve located in the oscillating line between the first location and the second end of the oscillating line.

3. The device of claim 1, further comprising:
an exhalation line having an inlet connected to the patient line.

4. The device of claim 3, further comprising:
a first check valve in the oscillating line between the first location and the second end of the oscillating line;
a second check valve in the exhalation line; and
wherein the exhalation line has an outlet connected to the oscillating line between the oscillator and the first location.

5. The device of claim 1, wherein the outlet valve is connected to the oscillating line.

16. The device of claim 15, wherein the bypass line is also connected to the outlet of the $CO_2$ scrubber

17. The device of claim 15, wherein the bypass line is also connected to the oscillating line.

18. A ventilating device, comprising:

an oscillator;

an oscillating line having a first end and a second end, the first end is in sealing relationship with the oscillator;

a gas supply line connected to the oscillating line at a first location and connected to a supply of gas;

a patient line connected to the second end of the oscillating line;

an exhalation line connected to the patient line; and

an outlet valve in the exhalation line and operable to release gas from the exhalation line during exhalation, and operable to close during inhalation.

19. The device of claim 18, further comprising a check valve located in the oscillating line between the first location and the second end of the oscillating line.

20. The device of claim 18, wherein the outlet valve comprises an actuator having a first flexible membrane disposed in the oscillating line, a second flexible membrane situated to selectively close an end of the exhalation line, and a pressure communicating line between the first and second membranes.

21. The device of claim 20, further comprising a control pressure line connected to the pressure communicating line.

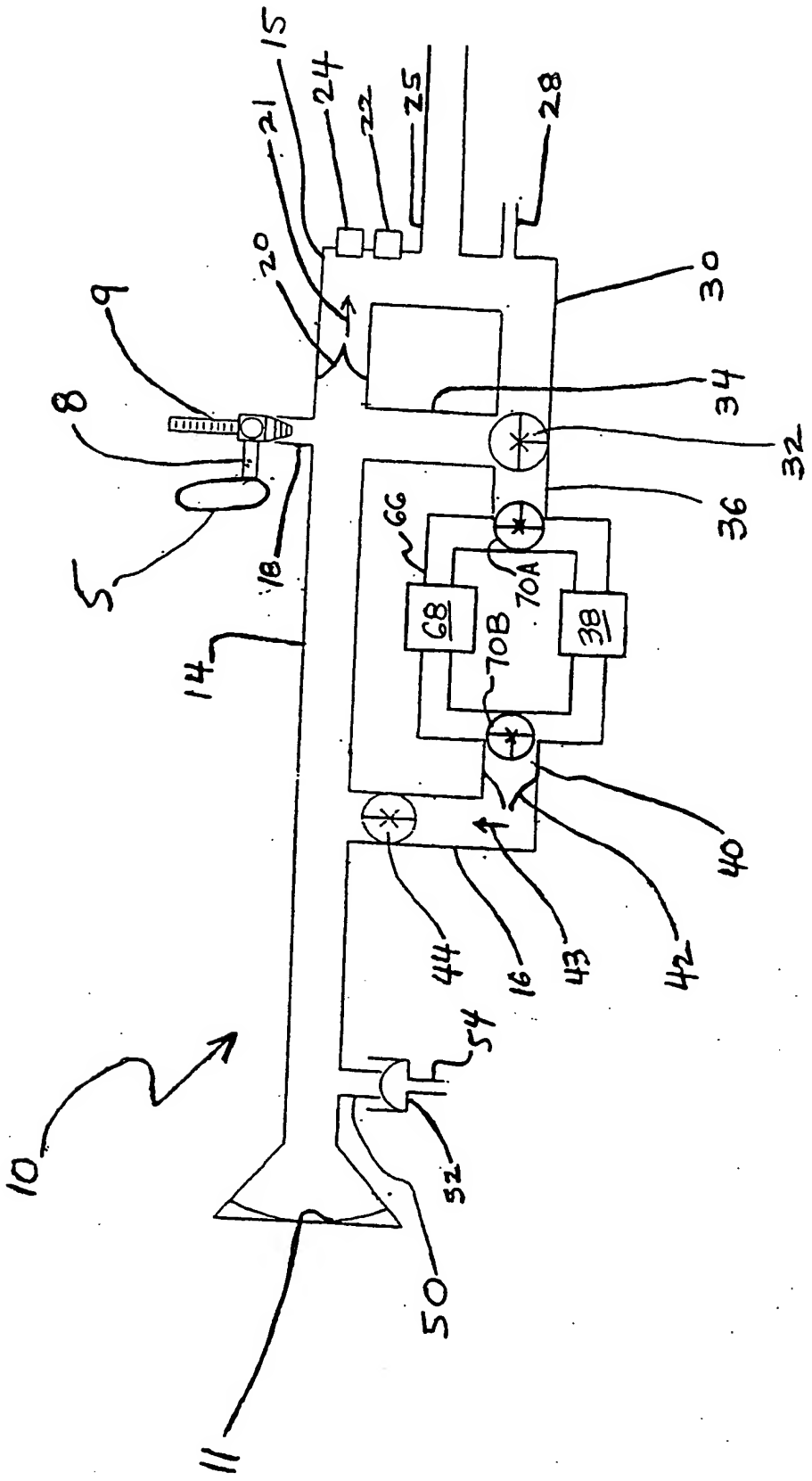
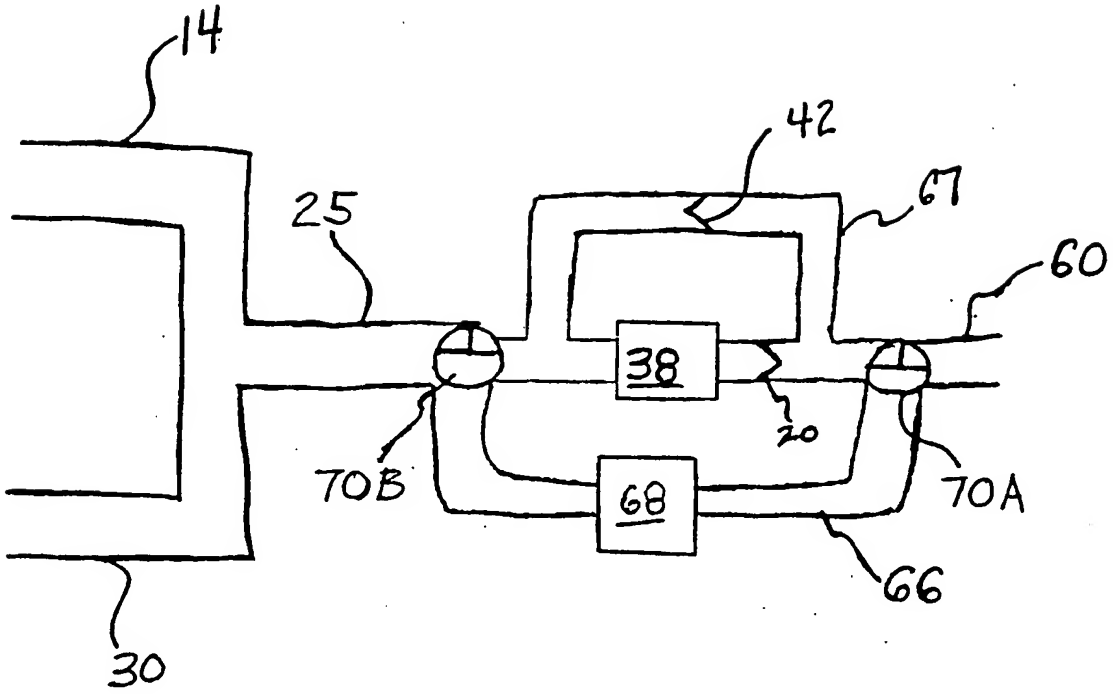

15
21
24
22
25
28
20
30
9
34
8
32
36
66
18
70A
68
38
70B
14
40
44
16
43
42
54
10
52
50
11

Figure 1

Fig 3a



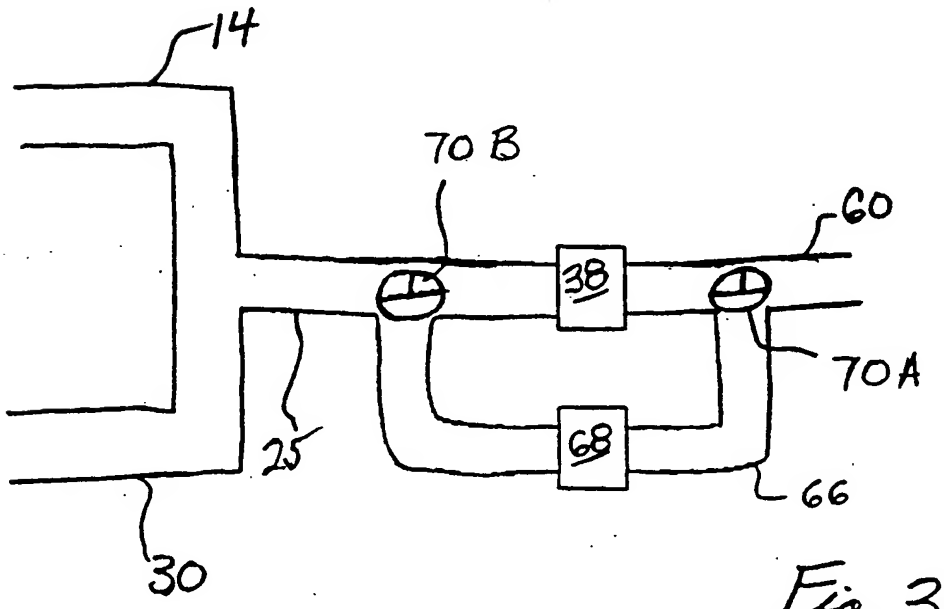
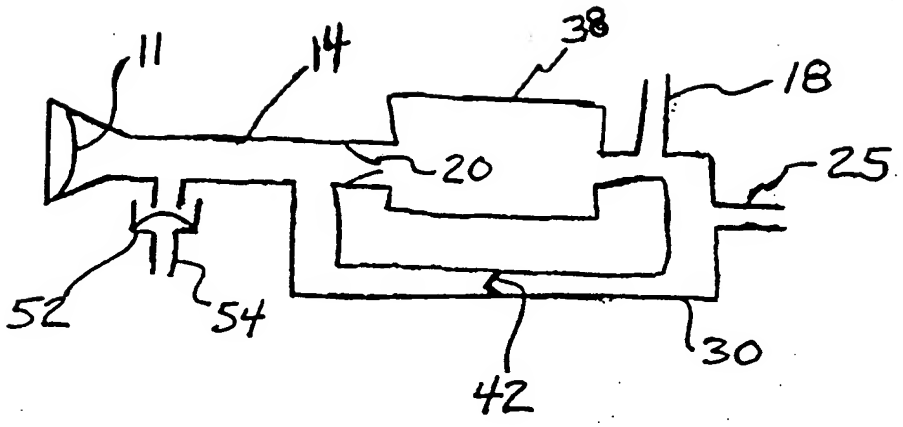




Fig 3b

Fig 5



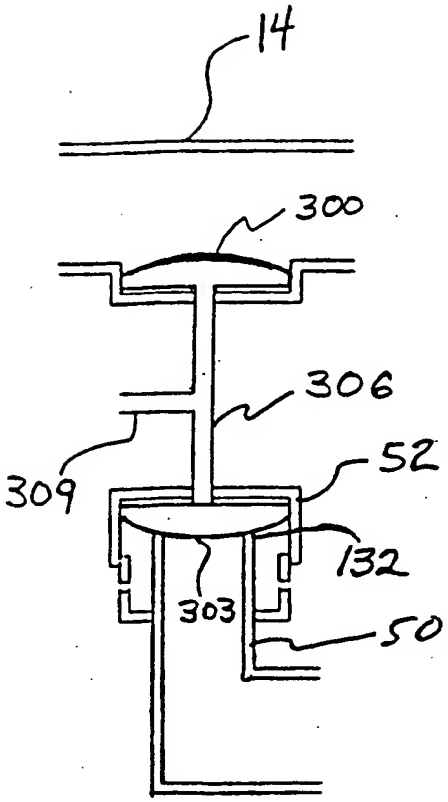



Figure 7a

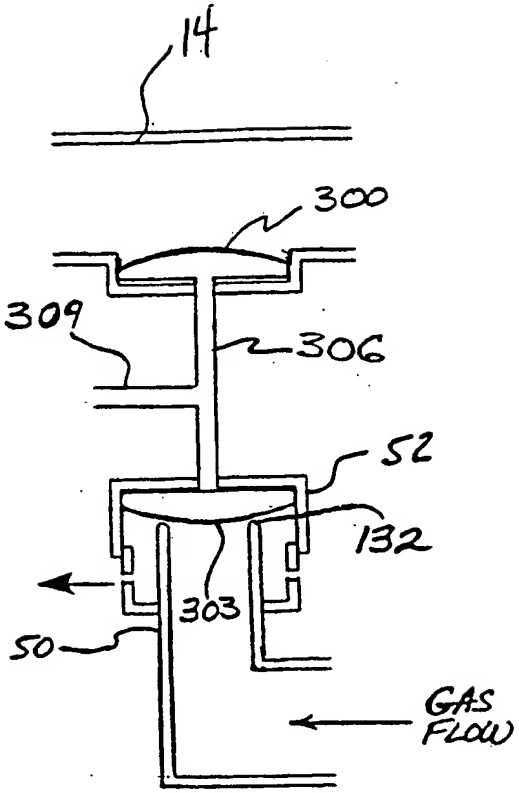



Figure 7b

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/21073

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61M 16/00; A62B 9/02
US CL :128/202.22, 204.18, 205.13
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/204.18, 202.22, 205.13, 204.28, 205.24, 205.28

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST
Search Terms: diaphragm, oscillator, scrubber, ventilator

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 5,850,835 A (TAKAKI et al.) 22 December 1998, entire document. | 1 |
| A | US 5,092,326 A (WINN et al.) 03 March 1992, entire document. | 1-3, 8, 9 |
| A | US 4,466,433 A (ROBBINS) 21 August 1984, entire document. | 1 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 13 SEPTEMBER 2000 | 10 OCT 2000 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231 | Authorized officer<br>MITAL B. PATEL |